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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,211	02/13/2004	Markku Anttila	2630-127	2487

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FITZPATRICK CELLA HARPER & SCINTO
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EXAMINER

GEMBEH, SHIRLEY V

ART UNIT	PAPER NUMBER
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1614

MAIL DATE	DELIVERY MODE
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09/07/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/777,211	Applicant(s) ANTTILA, MARKKU	
	Examiner Shirley V. Gembeh	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 7-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 7-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f):
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/16/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The response filed **3/2/07** presents remarks and arguments to the office action mailed **11/02/06**. Applicant's request for reconsideration of the rejection of claims in the last office action has been considered.

Applicants' arguments have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 3/16/07 is acknowledged and has been reviewed.

Status of claims:

Claims 1-5 and 7-9 are pending.

Claim 6 is cancelled.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 4 recites, "...the compound is administered at a time point which is in the range defined to begin at a time point during the food intake...". It is not clear what is meant by the above statement. Which time point is been referred to?

Maintained Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5 and 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Biskobing Expert Opinion Invest. Drug (of record) taken with of WO 97/32574 (of record) in view of Halonen et al. US 6,245,819(of record) further in view of Vasu, Council of Medical Research 2000 (newly applied).

Biskobing teaches administering the drug ospemifene (see abstract) to treat bone loss, however, fails to teach treating skin atrophy.

~~The~~ WO teaches the same compound, structurally identical to that of the claimed subject matter. The reference also teaches the compound can be taken with other active compounds. Thus food is can be active agent as it comprises nutrients for the functioning of the body.

Halonen et al (US'819 hereafter) teaches FC127a(=deaminohydroxytoremifene) as well as active metabolites, geometric isomers or stereoisomers thereof, (see col. 2 lines 35-59). US'819 teaches said compound and its medical use in the treatment

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of vaginal dryness and sexual dysfunction, see abstract. Thus one of ordinary skill in the art would have been motivated to use FC1271a of the prior art to treat skin atrophy.

Response

Applicant argues that it is common knowledge that food typically slows the action of a drug, with supporting evidence from Rowland et al., Clinical Pharmacokinetics Concepts and Applications Fatty food especially slows gastric emptying.

Contrary to Applicant's assertion, the claims do not recite any particular food. The claims require foodstuff having nutritional value and secretion of bile acids. Fat is of nutritional value. As evidenced by Vasu, the bioavailability of certain drugs is enhanced by food, especially drugs that are not readily absorbed orally, and further teaches that the presence of lipids (thus fat) stimulates bile secretion. See page 3, highlighted.

Applicant's argument has been fully considered but found unpersuasive. The teachings of the patent, do not exclude administration of the drug before, during or after. Some drugs are taken with food in order to prevent nausea, vomiting or other symptoms related to drug intake on an empty stomach. As cited by familydoc.org, not all medicines are affected by food intake. The general concept of why food can be taken before, after or during is discussed (see reference of record). Administration of drug with food is well known in the art of medicine.

Careful thought has been given to Applicants remarks, but are found unpersuasive.

The rejection is maintained as set forth in the office action of record.

Maintained Double Patenting

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Claims 1, 8-9 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent Application No. 11201098. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims require the compound-ospemifene is administered for the treatment of skin atrophy. As evident by Vasu, drugs are known in the art to be administered with food. With regard to Applicant's arguing that the disclosure is to enhancing bioavailability will not change treating atrophy, because as soon as the drug is available treating will proceed.

Claims 1-9 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6984665. Although the conflicting claims are not identical, they are not patentably distinct from each other. As evident by Vasu, drugs are known in the art to be administered with food. With regard to Applicant's arguing that the disclosure is to enhancing bioavailability, as soon as the drug is bioavailable, treating skin atrophy will proceed.

Applicant argues that none of the applications or the patents applied in the rejections contains disclosure of enhancing bioavailability.

The scope as a whole is the same. Administering the drug with or without food is not going to change the mechanism of action of the drug in the system. Once the drug gets in the system it is available to proceed with said treatment. It would have been

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reasonable to expect an efficacious treatment modality would occur following "enhanced" bioavailability of the compound –ospemifene.

Careful thought have been given to the remarks, but are found unpersuasive and the rejection is maintained as in the office action on record.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shirley V. Gembeh whose telephone number is 571-272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SVG
8/28/07

Frederick Krass
Primary Examiner
Art Unit 1614
